SEP - 7 2000

K 000997

Zortran™ Detector 510(k) Summary (Page 1 of 1)

Device trade name: Zortran™ Detector

Common name: Catheter Placement Verification Device

Device class and panel: 880.5970, Accessory to intravascular catheter, Class II

Applicant name:

Cynthia Pestka
Lucent Medical Systems, Inc.
135 Lake Street South, Suite 250
Kirkland, WA 98033
(425) 822-3310, x33 (phone)

Predicate device(s):

K922216 Ross Flexiflo® Tube Placement Verifier
K950017 Ross Flexiflo® Tube Placement Verifier
K940385 Navion (Bard) CathTrack® Catheter Location System
K901263 Navion (Bard) CathTrack® Catheter Location System
K983476 Navion (Bard) CathTrack (for enteral feeding tubes)
K884701 SIMS Deltec Cath-Finder® Catheter Tracking System
K960542 BioSense NOGA™
K870470 McCormick Laboratories, Inc. Trach-Mate®
K834265 McCormick Laboratories, Inc. Trach-Mate® (Original)

The Zortran and all of the substantially equivalent devices use magnetic signals to non-invasively determine the location of special catheters.

Device description:

The Zortran Detector is a battery or line powered (through the charger), hand held device which detects the location of a magnet-tipped catheter. A battery charger is also provided. The Zortran Detector uses only passive field sensors, and does not emit energy of any sort into the patient.

The Zortran Detector is designed (and labeled) to be used only with a compatible PICC or CVC intravascular catheter which contains one or more small, specially oriented magnets encapsulated at the distal end. It provides rapid feedback to a caregiver about the location and orientation of these magnet-tipped devices during or after initial placement.

Premarket Testing:

Type	Characteristics Tested	Results
Bench	Zortran accuracy	Meets accuracy claim
In Vitro	Leaching/degradation of magnet in HCl	Negligible leaching
Animal	Biocompatibility of magnet in rabbit stomach	Negligible reaction
Animal	PICC placement accuracy in swine	Ave. 4mm accuracy
Clinical	NG tube placement accuracy in humans	100% positive correlation with fluoroscopy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Cynthia Pestka
Director of Regulatory Affairs & Quality Assurance
Lucent Medical Systems, Incorporated
135 Lake Street South Suite 250
Kirkland, Washington 98033

Re: K000997
Trade Name: Zortran Detector
Regulatory Class: II
Product Code: FOZ
Dated: July 14, 2000
Received: July 17, 2000

Dear Ms. Pestka:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment #2
Statement of Intended Use

The Zortran™ Detector quickly locates and confirms the position of specially designed, magnet-tipped Peripherally Inserted Central Catheters (PICCs) and Central Venous Catheters (CVCs) during or after initial placement. This device may be used by appropriate caregivers in hospitals, long-term care facilities or home-care settings.

The Zortran provides rapid feedback to the caregiver, but was not designed to replace conventional methods of placement verification. Users are urged to confirm correct placement according to their established institutional protocol and clinical judgement.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000997